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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,362	09/16/2003	Roger Massengale	IFLOW.149A	1650

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,362

Applicant(s)

MASSENGALE ET AL.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/12/04, 3/24/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 17-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group (Group I elected), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/22/2006.

Currently claims 1-16 are pending for examination in this application with claims 1 and 7 being independent.

Information Disclosure Statement

The information disclosure statements (IDS) that were submitted on 4/12/2004 and 3/24/2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7-9 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed, Jr. (5,827,530). Reed, Jr. discloses a fillable patch for dermal or transdermal delivery.

Regarding claims 1, 3-5, 7-9 and 12-14, Reed, Jr. discloses a fluid medication delivery device comprising a fluid impermeable layer (26), a fluid semi-permeable layer

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(16, 28) wherein the two layers define a fluid reservoir space in between, a fluid inlet (32,34) comprising a valve that allows for fluid entry wherein the device is capable of perfusing liquid through the permeable layers when pressure is imparted on the fluid (col 3 ln 34-67, col 4 ln 1-44) (Figure 2). Additionally, the valve is configured to allow fluid to enter the reservoir but prevent fluid from exiting the fluid reservoir wherein the fluid reservoir comprises walls that are all heat sealed together (18, 20, 23) and also comprises a segmenting element (40) that defines a separate space in the reservoir (Figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 15-16 are rejected under 35 U.S.C 103(a) as being unpatentable over Reed, Jr. in view of Meconi et al. (5,770,220). Reed, Jr. meets the claim limitations

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as described above except for the materials disclosed and a semi permeable layer that is external to the fluid pouch.

However, Meconi et al. teaches an active substance-containing patch.

Regarding claims 6 and 15-16, Meconi et al. teaches a fluid delivery device that discloses a layer material to is selected from polyethylene, polysulfone, polyethersulfone, polyvinylidene difluoride, polycarbonate, nylon, HD polyethylene, and PTFE (col 2 ln 27-68, col 3 ln 1-46) wherein the semi permeable layer is located outside the fluid pouch (Figures 1-2).

At the time of the invention, it would have been obvious to use the semi permeable layer of Meconi et al. with the system of Reed, Jr. because the specific materials and structure allows for controlled fluid delivery by varying the material properties for diffusion. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Meconi et al.

Claim Rejections - 35 USC § 103

Claims 2 and 10-11 are rejected under 35 U.S.C 103(a) as being unpatentable over Reed, Jr.

Reed, Jr. discloses a fillable patch for dermal or transdermal delivery.

Regarding claims 2 and 10-11, Reed, Jr. discloses the claimed invention except for specific material dimensions (0.25 microns-0.254 mm) and pore sizes (0.25 micron) of the semi permeable layer and adjacent walls. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the semi

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permeable layer and walls with the pore sizes and dimensions as claimed by Applicant, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

10/13/06


CHRISTOPHER D. KOHARSKI
SUPERVISOR
TECHNICAL CENTER


Christopher D. Koharski
AU 3763